



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/709,796	05/28/2004	Michael A. Slivka	101896-251 (DEP5318)	3795
21125 7590 09/02/2010 NUTTER MCCLENNEN & FISH LLP SEAPORT WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			EXAMINER HOFFMAN, MARY C	
			ART UNIT 3733	PAPER NUMBER
			NOTIFICATION DATE 09/02/2010	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

Office Action Summary	Application No. 10/709,796	Applicant(s) SLIVKA ET AL.	
	Examiner MARY HOFFMAN	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-21, 23, 25, 27-35, 53 and 54 is/are pending in the application.
- 4a) Of the above claim(s) 13, 14, 19, 20 and 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-12, 15-18, 21, 23, 25, 27-31, 33-35, 53 and 54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 February 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7-9, 12, 15, 18, 21, 23, 25, 27-31, and 53-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young (U.S. Patent No. 6,626,906) in view of Lin (U.S. Patent No. 5,613,968). Also, see evidentiary reference to Shih et al. (U.S. Patent No. 6,136,002),

Young discloses a device (FIG. 6) for treating spinal deformities comprising a spinal anchoring element (9) adapted to seat a first spinal fixation element in a concave recess, the spinal anchoring element having a bore (14) extending therethrough; a fastening element (8) adapted to extend distally through the bore to mate the spinal anchoring element to bone; and a closure mechanism (10) adapted to mate to the spinal anchoring element to lock each of the first and second spinal fixation elements in a fixed position relative to the spinal anchoring element, the closure mechanism having a tapered bore (15) extending therethrough that axially aligns with the bore in the spinal anchoring element when the closure mechanism is mated to the spinal anchoring element, and a set screw (16) having a head that is received within the tapered bore in the closure mechanism, and a threaded shaft adapted to threadably engage threads in

Art Unit: 3733

the bore in the spinal anchoring element to mate the closure mechanism to the spinal anchoring element. The fastening element comprises a bone screw.

Young discloses the claimed invention except for a second spinal fixation element at a distance spaced apart from the first spinal fixation element, the spinal fixation elements in recesses in the spinal anchoring element; and the closure mechanism being removable (*i.e.* Young discloses an integral closure mechanism/spinal anchoring element instead of two separate pieces).

Lin discloses an embodiment with only a first spinal fixation element (FIG. 2) as well as embodiment that is modified to have a second spinal fixation element at a distance spaced apart from the first spinal fixation element (FIG. 4), when a plurality of spinal fixation elements/spinal rods are desired.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Young having a second spinal fixation element at a distance spaced apart from the first spinal fixation element in view of Lin to provide a plurality of spinal fixation elements when more spinal fixation elements are desired, and since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Young with the closure mechanism being removable from the spinal anchoring element (*i.e.* the closure mechanism being non-integral with the spinal anchoring element), since it has been held that constructing a

Art Unit: 3733

formerly integral structure in various elements involves only routine skill in the art.

Nerwin v. Erlichman, 168 USPQ 177, 179. In this case, having a separate closure mechanism could provide benefits, such as making removal of the rod ref. #2 easier during surgical revision, and also making it easier to replace closure mechanism ref. #6 if the closure mechanism was accidentally damaged during insertion of the rod without having to replace the entire piece (closure mechanism and spinal anchoring element). Also, see evidentiary reference to Shih et al. (U.S. Patent No. 6,136,002), which shows that clamps meant for holding rods can be constructed as two separate pieces, closure mechanism (ref. #14) and spinal anchoring element (ref. #12).

Young in view of Lin discloses a central portion positioned between the first and second recesses and adapted to receive the fastening element for mating the anchoring element to bone. The central portion includes the bore extending therethrough. The closure mechanism includes a central portion adapted to receive the set screw for mating the closure mechanism to the spinal anchoring element. The first recess is formed in a first end portion of the spinal anchoring element and the second recess is formed in a second, opposed end portion of the spinal anchoring element. Each portion includes a superior surface and an inferior surface, the first and second recesses being formed in the superior surface. The closure mechanism includes a first end portion and a second end portion

Claims 10-11 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young (U.S. Patent No. 6,626,906) in view of Lin (U.S. Patent No. 5,613,968) further in view of Shih et al. (US 6,136,002).

Art Unit: 3733

Young in view of Lin discloses the claimed invention except for bone engaging members (spikes) extending distally from the inferior surface of each of the first and second end portions.

Shih et al. disclose bone engaging members (spikes) extending distally from the inferior surface of each of the first and second end portions for gripping bone.

It would have been obvious at the time the invention was made to construct the fixation elements of Young in view of Lin discloses with bone engaging members (spikes) extending distally from the inferior surface of each of the first and second end portions in view of Shih et al. to grip bone.

Claims 16-17 and 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young (U.S. Patent No. 6,626,906) in view of Lin (U.S. Patent No. 5,613,968) further in view of Paul et al. (US 2004/0236327).

Young in view of Lin discloses the claimed invention except for each spinal fixation element being flexible and being formed from a bioabsorbable material.

Paul et al. disclose spinal fixation element being flexible and being formed from a bioabsorbable material (paragraph [0097]) to provide an improved spinal fixation element.

It would have been obvious at the time the invention was made to construct the fixation elements of Young in view of Lin being flexible and bioabsorbable in view of Paul et al. to provide a spinal improved fixation element.

Response to Arguments

Applicant's arguments filed 06/15/2010 have been fully considered but they are not persuasive. Currently, the claims do not positively recite that the fastening element is a polyaxial fastening element, or capable of polyaxial movement while extending distally through the bore. Rather, the claims recite that the set screw is configured, *i.e.* capable of, preventing polyaxial movement. The set screw is capable of preventing polyaxial movement, or any other movement, of the fastening element by securing it within the bore. The examiner invites Applicant to contact the examiner to discuss specific amendments regarding the polyaxial nature of the fastening element to overcome the current rejection and to possibly result in an examiner's amendment.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 3733

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARY HOFFMAN whose telephone number is (571)272-5566. The examiner can normally be reached on Monday-Thursday 10:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary C. Hoffman/
Examiner, Art Unit 3733
/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733

Application/Control Number: 10/709,796
Art Unit: 3733

Page 8